UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



MEMORANDUM

6/5/2018

SUBJECT: Acute Toxicity Review for CURoxide, EPA Reg. No.: 93324-R

FROM: Ian Blackwell

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

Jenny Tao, Senior Scientist/Team Leader (Acute Toxicology) THRU:

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TO: Zeno Bain, PM Team 33 / Zebora Johnson

> Regulatory Management Branch I Antimicrobials Division (7510P)

Registrant: Curis System Submission No.: 1016549 E-Sub No.: 27167 Decision No.: 538942 DP No.: 446486 Action Code: A532 MRID No(s).: 50526604

Formulation from label				
PC code(s)	CAS #(s)	Active Ingredient(s) % weigh		
000595	7722-84-1	Hydrogen Peroxide	7	
		Other Ingredients	93	
		Total	100	

I) <u>BACKGROUND</u>: The registrant, Curis System, has submitted an application for pesticide registration for their product: CURoxide, EPA Reg. No. 93324-R. To support the acute toxicity data requirements of 93324-R, the registrant is claiming that the proposed product is "similar" to Reg. No. 90150-2. and citing acute toxicity data from the Agency's Reregistration Eligibility Decision (RED) for Peroxy Compounds (December 1993) as well as published literature (MRID 50526604). The proposed product, File Symbol 93324-R, contains 7.0% hydrogen peroxide while the cited product, Reg. No. 90150-2, contains 7.8% of that same active ingredient. The proposed product is a new end use antimicrobial fogging/misting sterilant for spaces and rooms in commercial, industrial, and institutional settings. It is also intended to be used for disinfection/deodorization/cleaning of dry, pre-cleaned, hard, non-porous, food and non-food contact surfaces in commercial, industrial, institutional, and residential settings by direct spray. Areas of use include "homes, vehicles, school & daycare, gyms & locker rooms, sports gear, hospitals, nursing homes, assisted living, long term care, rehab facilities, food transport vehicle, laundry rooms, veterinary, pharmacies, transportation, buses, trains, transit, ambulance, barber shops, laboratories, restaurants, boats, ships, federally inspected meat & poultry processing plants, farms, animal pens and poultry houses, egg processing premises, hatcheries, swine premise sanitation, refrigerated storage units (empty & disconnected), airplanes, automobiles" as well as toys and staffed animals according to the proposed label.

II) <u>FINDINGS/RECOMMENDATIONS</u>: The Chemistry and Toxicology Team (CTT) bridges acute toxicity data down from Reg. No. 90150-2 to cover the acute toxicity data requirements of File Symbol 93324-R. We feel that the acute toxicity profile of 90150-2 will be suitable to determine precautionary labeling for the proposed product File Symbol 93324-R.

Reg. No.	Amount of Active (Hydrogen Peroxide)
93324-R	7.0%
90150-2	7.8%

III) The acute toxicity profile of *CURoxide*, EPA Reg. No. 93324-R, is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	50526604	IV	Cited*
Acute Dermal Toxicity	50526604	III	Cited*
Acute Inhalation Toxicity	50526604	IV	Cited*
Primary Eye Irritation	50526604	I	Cited*
Primary Skin Irritation	50526604	IV	Cited*
Dermal Sensitization	50526604	Nonsensitizer	Cited*

^{*} Citing the acute toxicity profile of EPA Reg. No. 90150-2

IV) PRODUCT LABELING

- 1) Signal Word: DANGER
- 2) The statement, "Keep Out of Reach of Children (KOROC)", is required. It should appear immediately above the front-panel signal word "DANGER".
- 3) The Agency's Label Review Manual (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf) indicates the following human-hazard precautionary statements:

4) PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

"Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Avoid breathing vapor or spray mist. Do not get in eyes, skin, or on clothing. Avoid contact with skin. Wear goggles, safety glasses or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

PERSONAL PROTECTIVE EQUIPMENT (PPE):

The following PPE is recommended:

- Protective eyewear such as goggles or face shield, or safety glasses
- Require at least half-face piece respirator (and appropriate eye protection)
 with either 3M 6003 or 6006 (organic vapor/acid gas or multigas cartridge in
 combination with particulate filter (i.e., 5N11 or 5P71), if hydrogen peroxide
 levels ≥1 ppm for re-entry the treated room
- Gloves, long sleeves, and long pants.

Final selection of additional PPE must be done in accordance with hospital/site guidelines and take into consideration the use of the product as well as any infection or exposure hazards related to the environment to be disinfected.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

5) First Aid Statements:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

6) This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified

- hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.
- 7) Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon **use sites**, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions.

Note to PM/CRM/Registrant: The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.